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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/521,907	03/09/00	LYNGSTADAAS	S 49121

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INTELLECTUAL PROPERTY PRACTICE GROUP
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EXAMINER	
EWOLDT,G	
ART UNIT	PAPER NUMBER
1644	8

DATE MAILED: 08/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/521,907	Lyngstadaas et al
Examiner	**Art Unit**
G. R. Ewoldt	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 22, 2001*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *28-59* is/are pending in the application.

4a) Of the above, claim(s) *36-40 and 56-59* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *28-35 and 41-55* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☒ Other: *Notice to Comply, Sequence*

DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 28-56, and the species skin graft, amelogenins, and propylene glycol alginate (PGA), in Paper No. 8, filed 5/22/01, is acknowledged. Applicant argues that the search of Groups I and II together would pose no undue search burden.

These argument are not found persuasive for the following reasons. The methods of Groups I and II are patentably distinct, as set forth in Paper No.5, comprising significantly different fields of search. As such, restriction is proper.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 57-59 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions. Claims 36-40 and 56 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected species of the elected invention.

Claims 28-35 and 41-55 read on the elected invention and are being acted upon.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. Specifically, the sequences on page 12 of the specification must be brought into sequence compliance and identified by SEQ ID NOS:.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 41 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

A) in claim 41, the metes and bounds of the claim are indefinite because the use of "or" before both "enamel matrix proteins" and "mixtures thereof" makes it unclear whether "mixtures thereof" includes mixtures of "enamel matrix proteins",

B) in claim 42, the metes and bounds of the claim are indefinite because the use of "and" before both "derivatives thereof" and "mixtures thereof" makes it unclear whether "mixtures thereof" includes mixtures of "derivatives". Additionally, the phrase "amelins (ameloblastin, sheathlin)," is an improper use of a parenthetical phrase within a claim. If Applicant desires to place limitations on the "amelins" of the claim, said limitations should be recited in an additional dependent claim.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 28-35 and 41-55 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Carlson-Mann et al. (1998) in view of U.S. Patent No. 6,022,862 (2000), as evidenced by Palaiologou et al. (2001).

Carlson-Mann et al. teaches a method of using an active enamel substance comprising a mixture of amelogenins of up to about 120 kDa, or 100 kDa, or 60 kDa, wherein the major active enamel substance has a molecular weight of about 20 kDa, in a PGA solution (Emdogain™), to promote the regrowth of periodontal tissues including periodontal ligament (see particularly page 178 column 1, paragraph 6 and **Procedure**).

Carlson-Mann et al. differs from the claimed invention in that it does not teach a method of promoting the take of a skin graft, said graft comprising an autogeneous graft, a full-thickness graft, a split-thickness graft, a composite graft, a seed graft, or a mesh graft.

The '862 patent teaches the desirability of stimulating the growth of fibroblasts to promote the healing of a skin graft (see particularly column 3, lines 43-57 and column 11, lines 29-54).

From the teachings of the references it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a method of using an active enamel substance comprising a mixture of amelogenins of up to about 120 kDa, or 100 kDa, or 60 kDa, wherein the major active

enamel substance has a molecular weight of about 20 kDa, in a PGA solution (Emdogain™), to promote the take of a skin graft, said graft comprising an autogeneous graft, a full-thickness graft, a split-thickness graft, a composite graft, a seed graft, or a mesh graft, given the fact that Emdogain™ promotes the regrowth periodontal ligament and periodontal ligament comprises predominantly fibroblasts, as taught by Carlson-Mann et al. and evidenced by Palaiologou et al. (Abstract). Note that "promoting the take of a graft" is defined in the specification to include promoting the "proliferation of fibroblasts," which the reference teaches is a property of Emdogain™. One of ordinary skill in the art would have been motivated to perform the claimed method substituting a skin graft for a periodontal graft because the '862 patent teaches the desirability of stimulating the growth of fibroblasts to promote the healing of a skin graft. Note that active enamel substances (Emdogain™) were known to promote the proliferation of fibroblasts, as taught by Carlson-Mann et al., and that Emdogain™ was the active enamel substance used in the examples disclosed in the specification (see Materials and Methods, page 23). Thus, the properties of the active enamel substance recited in the claims (i.e., claims 41-53), as well as the concentrations of active enamel substance administered (i.e., claim 29), are inherent properties of Emdogain™. Additionally, the timing of administration of the active enamel substance (i.e., claims 30 and 31) comprises routine optimization and is well within the purview of one of skill in the art.

8. Claims 28-35, 41-47, and 50-55 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hammarstrom et al. (1997) in view of U.S. Patent No. 6,022,862 (2000).

Hammarstrom et al. teaches a method of using an active enamel substance comprising a mixture of amelogenins of up to about 120 kDa, or 100 kDa, or 60 kDa, to promote the regrowth of periodontal tissues including periodontal ligament fibroblasts (see particularly page 671 column 3, paragraph 2 and page 675 column 3, paragraph 2).

Hammarstrom et al. differs from the claimed invention in that it does not teach a method of promoting the take of a skin graft, said graft comprising an autogeneous graft, a full-thickness graft, a split-thickness graft, a composite graft, a seed graft, or a mesh graft.

The '862 patent teaches the desirability of stimulating the growth of fibroblasts to promote the healing of a skin graft (see particularly column 3, lines 43-57 and column 11, lines 29-54).

From the teachings of the reference it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a method of using an active enamel substance comprising a mixture of amelogenins of up to about 120 kDa, or 100 kDa, or 60 kDa, in a PGA solution, to promote the take of a graft, as taught by Hammarstrom et al., substituting a skin graft, said graft comprising an autogeneous graft, a full-thickness graft, a split-thickness graft, a composite graft, a seed graft, or a mesh graft, given the facts that the Hammarstrom et al. reference teaches that an active enamel substance in PGA promotes the regrowth of periodontal ligament fibroblasts and that the '862 patent teaches the desirability of stimulating the growth of fibroblasts to promote the healing of a skin graft. Note that "promoting the take of a graft" is defined in the specification to include promoting the "proliferation of fibroblasts," which the Hammarstrom et al. teaches is a property of an active enamel substance in PGA. One of ordinary skill in the art would have been motivated to perform the claimed method of promoting the take of a skin graft by administering an active enamel substance because active enamel substances were known to promote the proliferation of fibroblasts, as taught by the Hammarstrom et al., and the promotion of fibroblast growth was known to be desirable in the healing of skin grafts, as taught by the '862 patent. Further note the properties of the active enamel substance in PGA recited in the claims (i.e., claims 41-53), as well as the concentrations of active enamel substance administered (i.e., claim 29), are inherent properties of an active enamel substance in PGA because a composition can not be separated from its own properties. Additionally, the timing of administration of the active enamel substance (i.e., claims 30 and 31) comprises routine optimization and are well within the purview of one of skill in the art.

9. No claim is allowed.

10. References CH-CN on the form PTO-1449, filed 1/22/01 have been lined through and have not been considered because they have not been provided.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805 The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful,

the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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August 27, 2001

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